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Petroleum Jelly (Vaseline Balls) for the Treatment of Constipation: A Survey of Hospice and Palliative Care Practitioners

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Abstract

Constipation is a common symptom at end of life, impacting patient outcomes and healthcare costs. Hospice and palliative care professionals often use practices based on anecdotal evidence. One such intervention is an oral preparation of petroleum jelly (OPJ), referred to as "Vaseline balls." This survey was designed to collect information regarding healthcare practitioners' knowledge and attitudes toward the use of OPJ for the management of constipation in hospice and palliative care. An online survey was distributed to physicians, nurse practitioners, nurses, and pharmacists who work with hospice and palliative care patients. A total of 67% (n=237/353) of responders reported being familiar with the use of OPJ. Results indicate there is a need for further clinical research on the use of OPJ to guide practice.

Keywords

Vaseline balls, mineral oil, constipation, oral petroleum jelly, hospice, palliative care

Introduction

Constipation is a common symptom at the end of life, impacting both patient outcomes and health care costs. In a national retrospective chart review of over 50 000 hospice patients, 22% of the patients reported having some level of constipation during their hospice stay regardless of terminal diagnosis.[1] A separate study involving hospice patients with cancer found a stronger negative correlation between constipation and quality of life than between pain and quality of life.[2] Constipation may be pharmacologically managed with the administration of stimulant laxatives, osmotic laxatives, surfactants, bulk forming agents, or lubricants.

Mineral oil is a lubricating agent that can be administered orally or as a rectal enema. The onset of action of oral mineral oil is approximately 6 to 8 hours. Onset of action of rectal mineral oil is approximately 2 to 15 minutes.[3] Mineral oil facilitates bowel movements by coating the intestine to lubricate and decrease colonic absorption of fecal water. Mineral oil is indicated for fecal impaction and treatment of occasional constipation in patients where straining must be avoided. Rectal mineral oil may remove part or all contents of the rectum, sigmoid, and/or part of the descending colon.[4] For impacted fecal matter higher in the colon, oral mineral oil may be used. Routine use of oral mineral oil may decrease the absorption of fat-soluble vitamins, although studies in pediatric patients demonstrated no clinically significant reduction in serum levels of vitamin A or vitamin E.[5,6] When given orally, mineral oil also carries the risk of aspiration lipoid pneumonia in pediatric and debilitated adult patients.[7,8]

A potential alternative to oral mineral oil for gastrointestinal lubrication is a form of oral petroleum jelly (OPJ), commonly referred to as "Vaseline balls." The OPJ have been used for hospice and palliative care patients with constipation who have failed conventional modes of therapy. Petroleum jelly (Vaseline) can be chilled and rolled into small round balls and coated with flavoring to be ingested by patients.[9] The melting point of petroleum jelly is about 100.4°F, which is similar to the normal gastric temperature.[10,11] This property allows petroleum jelly to become liquid once in the gastrointestinal tract, mimicking the activity of oral mineral oil. The risk of aspiration may be reduced with the use of OPJ, because petroleum jelly is a

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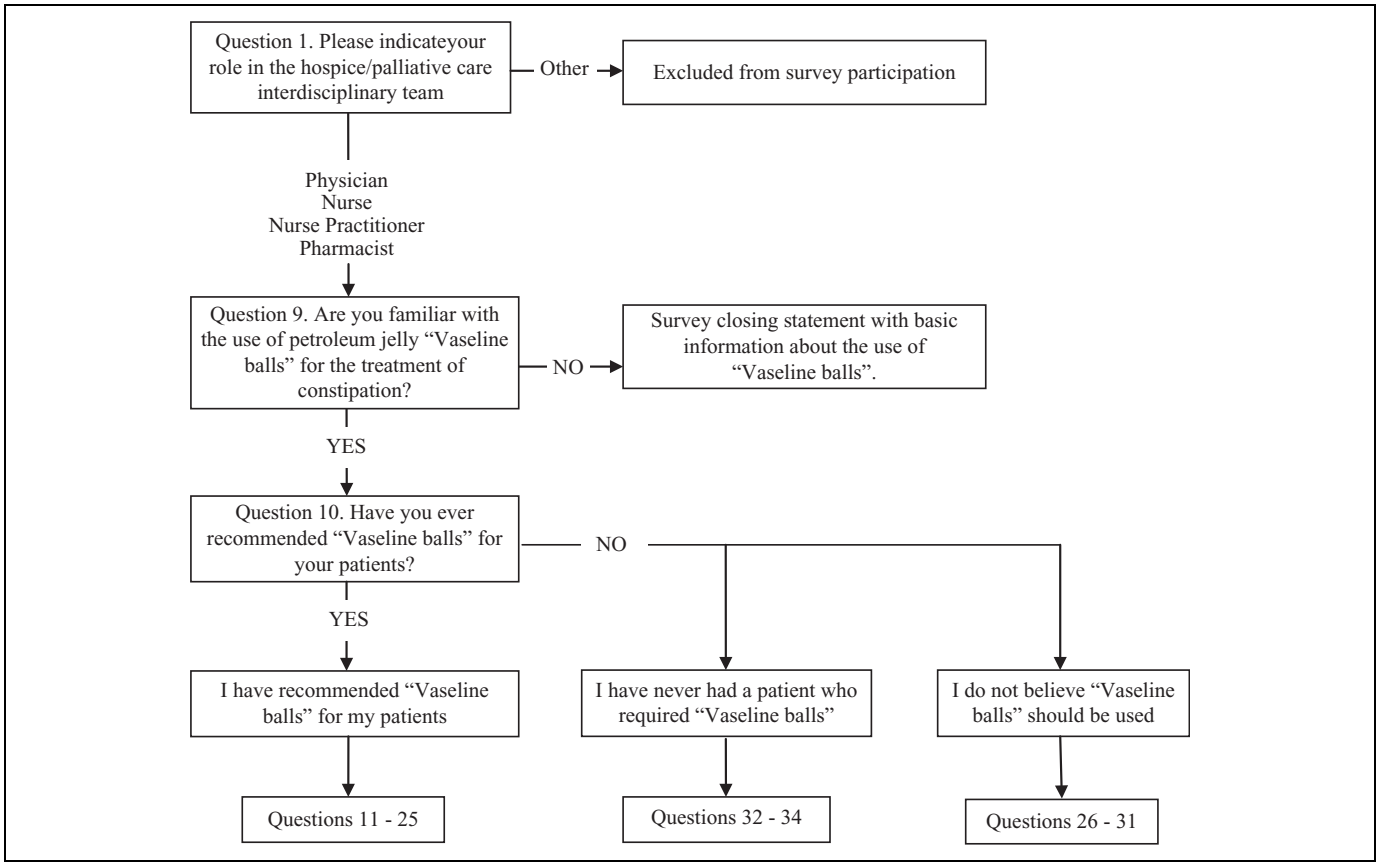
Question 1. Please indicateyour role in the hospice/palliative care interdisciplinary team
Other
Excluded from survey participation
Physician
Nurse
Nurse Practitioner
Pharmacist
Question 9. Are you familiar with the use of petroleum jelly "Vaseline balls" for the treatment of constipation?
NO
Survey closing statement with basic information about the use of "Vaseline balls".
YES
Question 10. Have you ever recommended "Vaseline balls" for your patients?
NO
YES
I have recommended "Vaseline balls" for my patients
I have never had a patient who required "Vaseline balls"
I do not believe "Vaseline balls" should be used
Questions 11 - 25
Questions 32 - 34
Questions 26 - 31

Figure 1. Survey skip logic sequence.

soft-solid form of petrolatum and is swallowed whole like a pill or capsule. The OPJ has been discussed in the treatment of high impaction, a form of constipation in which stool remains in the ascending and transverse colon, causing loss of appetite, nausea and vomiting, abdominal distention, and cramping.[12] To date, there are no clinical studies or peer-reviewed journal articles evaluating the use of OPJ in clinical practice.[9] The goal of this study was to determine hospice and palliative care practitioners' familiarity with and opinions on the use of OPJ for constipation in their patients.

Methods

An online survey of hospice and palliative care practitioners was conducted using a convenience sample of eligible practitioners. A 34-item questionnaire was developed using a Web-based survey system that allows for anonymous participation (Qualtrics Survey Software, Qualtrics, Provo, UT, USA). All questions were multiple choice or multiselect. Where appropriate, an option to select ''other'' and provide a free-text response was available. Questions covered demographic information, practitioner familiarity with OPJ, and assessed attitude and experience with OPJ. Skip logic directed eligible participants to the appropriate survey sequence based on initial familiarity responses (Figure 1). Survey respondents who were not familiar with the use of OPJ were provided with a brief overview of the intervention with no additional survey questions.

Practitioners who were familiar with OPJ and had recommended them were asked questions about patient selection, type of constipation, and place in therapy. Additional questions covered dosing, effectiveness, tolerability, and OPJ preparation. For the purpose of this study, place in therapy was categorized as first, second, or third line. Second-line therapy was defined as OPJ used to treat constipation refractory to 1 to 2 laxatives, while third-line therapy was defined as OPJ used to treat constipation refractory to oral laxatives, suppositories, and/or enemas. For the participants, effectiveness was defined as the percentage of patients who had a bowel movement with the use of OPJ. ''Very effective'' was defined as stimulating a bowel movement in at least 75% of the patients, ''effective'' indicated a bowel movement in 50% to 74%, and ''somewhat effective'' indicated a bowel movement in 25% to 49% of the patients. Lower response rates were defined as ''not effective.'' Participants were also asked to estimate time to bowel movement. Practitioners who were familiar with OPJ but never had a patient who required them were asked when they would recommend OPJ.

Survey respondents who believed OPJ should not be used were asked why they oppose OPJ use, what adverse effects they expected, how they learned about OPJ, and their level of comfort with the use of oral mineral oil for their patients. Six

Table 1. Survey Respondent Demographics.

	Have recommended (%) n = 149	Have not needed to recommend (%) n = 76	Do not agree with use (%) n = 12	Not familiar (%) n = 116	Total responses (%) n = 353
Type of practitioner					
Physician	14 (9)	16 (21)	2 (17)	30 (26)	68 (17)
Nurse (RN, LPN)	104 (70)	45 (59)	4 (33)	66 (57)	225 (57)
Nurse practitioner	12 (8)	11 (14)	5 (42)	17 (15)	47 (12)
Pharmacist	19 (13)	4 (5)	1 (8)	3 (3)	30 (8)
Years in practice					
<1 year	–	1 (1)	–	1 (1)	3 (1)
1-2 years	1 (1)	1 (1)	–	8 (7)	11 (3)
3-5 years	16 (11)	2 (3)	–	11 (9)	31 (9)
6-10 years	14 (9)	14 (18)	–	14 (12)	43 (12)
>10 years	118 (79)	58 (76)	12 (100)	82 (71)	271 (75)
Years in hospice and palliative care					
<1 year	1 (1)	4 (5)	–	15 (13)	23 (6)
1-2 years	12 (8)	12 (16)	–	12 (10)	37 (10)
3-5 years	30 (20)	15 (20)	1 (8)	29 (25)	77 (21)
6-10 years	44 (30)	20 (26)	2 (17)	24 (21)	90 (25)
>10 years	62 (42)	25 (33)	9 (75)	36 (31)	132 (37)
Country of practice					
United States					335 (95)
North East	18 (12)	12 (16)	3 (25)	19 (16)	52 (15)
Midwest	46 (31)	21 (28)	4 (33)	29 (25)	100 (28)
South	59 (40)	30 (40)	1 (8)	40 (34)	130 (37)
West	26 (17)	11 (14)	4 (33)	11 (9)	52 (15)
Unknown	–	–	–	1 (1)	1 (0)
International		2 (2)		16 (14)	18 (5)
Area of practice					
Urban/suburban	55 (37)	42 (55)	9 (75)	49 (42)	155 (44)
Small town	25 (17)	8 (11)	–	26 (22)	59 (17)
Isolated rural area	11 (7)	6 (8)	–	6 (5)	23 (7)
Mixed	58 (39)	20 (26)	3 (25)	35 (30)	116 (33)
Average daily census reported					
1-25	6 (4)	10 (13)	1 (8)	29 (25)	46 (13)
26-100	50 (34)	27 (36)	1 (8)	26 (22)	104 (29)
>100	66 (44)	27 (36)	7 (58)	32 (28)	132 (37)
Unknown	4 (3)	–	–	3 (3)	7 (2)
Not applicable	23 (15)	12 (16)	3 (25)	26 (22)	64 (18)

Abbreviations: RN, registered nurse; LPN, licensed practical nurse.

potential reasons for opposing OPJ were offered as possible choices. Practitioners were given the additional option to list alternate reasons for opposition. Practitioners who had recommended OPJ and those who opposed the use of OPJ were asked specifically about adverse events. Practitioners who had witnessed any adverse event in their patients and practitioners who were against OPJ use were given a list of potential adverse events along with space for free-text responses. The list of potential adverse events provided for OPJ was extrapolated from the adverse event profile of oral mineral oil.

This survey was deemed exempt by The Ohio State University institutional review board. Physicians, nurse practitioners, nurses, and pharmacists who work with hospice and palliative care patients met inclusion criteria to participate in this study. The investigators calculated that at least 270 practitioners would need to be surveyed to achieve a 90% confidence interval with a 5% margin of error. Requests for participation were distributed via hospice and palliative care websites and through national and state hospice organizations with a link to the survey homepage. In addition, an invitation to participate in the survey was distributed via e-mail and facsimile to 340 unique hospice locations across the United States who partner with a national pharmacy benefits provider. The survey remained open for 4 consecutive months, November 10, 2012 to March 11, 2013. Descriptive statistics were generated for all survey items. Categorical responses were expressed using frequencies and percentages.

Results

After publishing the survey online, 397 individuals responded. Of 397 respondents, 27 (7%) did not self-identify as a pharmacist, physician, nurse, or nurse practitioner and were ineligible for survey participation. The remaining 370 practitioners met inclusion criteria noting that respondents were not required to answer all survey questions to be included in the data analysis.

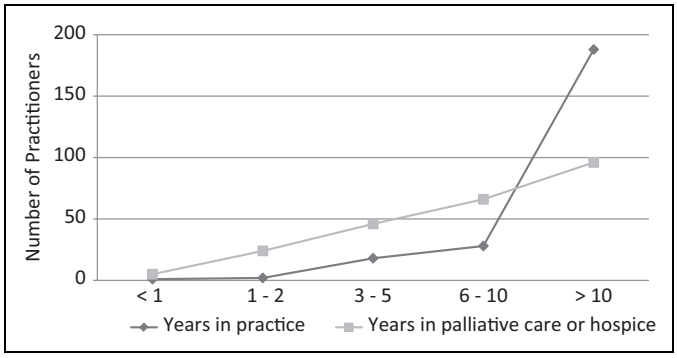

Figure 2. Practitioner familiarity with oral petroleum jelly based on years of experience.

In all, 17 respondents abandoned the survey during the demographic questions leaving 353 practitioners who completed the survey. Demographic information is given in Table 1. The majority (95%) of the survey responses were from the United States; there were 18 (5%) international responses. Geographically, the southern United States had the most responses, followed by the Midwest. There were 9 states within the United States which had no survey respondents, 6 of those states were from the western region, as defined by the US census.[13]

Overall, 237 (67%) health care practitioners reported familiarity with the use of OPJ. Of the 18 international responses, only 2 practitioners (both from Canada) reported being familiar with OPJ. All other practitioners familiar with OPJ practiced in the United States. A total of 79% (188 of 237) of the respondents who were familiar with OPJ had been a health care practitioner for more than 10 years. There appears to be a correlation between years in practice and familiarity with OPJ. The percentage of practitioners who were familiar with OPJ increased as the number of years in practice and number of years working specifically in hospice and palliative care increased (Figure 2). The majority of practitioners who were familiar with OPJ reported "I have recommended "Vaseline balls" for my patients." Only 12 of the practitioners familiar with OPJ responded "I do not believe "Vaseline balls" should be used."

In total, 149 (63%) practitioners recommended OPJ for their patients. These practitioners were primarily from the South (40%) and Midwest (31%), and the group was heavily comprised of nurses (70%). The majority (91%) of practitioners who recommended OPJ had been practicing hospice and palliative care for at least 3 years. There did not appear to be a difference in OPJ use based on the area of residence of most patients (urban/suburban, rural, isolated rural, or mixed). Survey respondents did not limit recommendations for OPJ to suspected cases of high impaction, although high impaction and hard stool in the rectum were the most described forms of constipation targeted. Most respondents reported use for more than one form of constipation, and some practitioners (n = 12, 8%) did not recommend OPJ for high impaction or hard stool in the rectum but reported other uses.

All practitioners who recommend OPJ report using them in adult patients, although 7% also recommend OPJ for pediatric patients. The OPJ has been recommended at all stages of therapy but was most commonly recommended for constipation refractory to oral laxatives, suppositories, and/or enemas (Table 2). Based on its use for more refractory cases, the majority of the practitioners who had experience with OPJ recommended it for less than 10% of their patients with constipation. Most practitioners (n = 108) recommend 0.25-in diameter round (pea size) balls for administering OPJ. Other practitioners (n = 28) reported varying sizes with the most common being 0.5-inch diameter (marble size) balls.

Powdered sugar was the most common reported coating (56%) for OPJ. Other coatings include granulated sugar, cinnamon sugar, cocoa mix, favored gelatin mix, and other powered drink mixes. Although a coating may help to make OPJ more palatable, 9 survey practitioners recommended administering OPJ without a coating. All but 1 practitioner recommended either frozen (80%) or refrigerated (19%) petroleum jelly to aid preparation and administration.

Although patterns of patient selection for OPJ use were relatively consistent among practitioners, results demonstrate a lack of consistency in the amount of OPJ recommended. Dosing was primarily reported as the number of OPJ balls, with 91% of practitioners recommending between 1 and 4 balls per dose at varying intervals. Daily dosing of OPJ was most commonly recommended (88%), but some described administering OPJ as frequently as every 2 hours until bowel movement. Outside of the results described earlier, there was no uniformity of recommendations regarding the dose or dosing interval of OPJ. A few practitioners mentioned calculating the dose based on tablespoons or teaspoons of petroleum jelly to be broken down into smaller balls, and several practitioners described different dose limits. When the data for recommended dose were broken down by discipline (nursing, pharmacy, or medicine), the lack of consistency in dose and frequency remained.

Of the respondents, 87% described OPJ as effective or very effective, and 88% report the intervention effectively produces a bowel movement within 24 hours of administration. There was very little variation in the percentage of practitioners who describe OPJ as effective or very effective based on the type of constipation. Only 2 practitioners considered OPJ as an ineffective intervention. The OPJ was continued for less than 1 week in the majority of patients. The most common reason for discontinuing therapy was the presence of ongoing bowel movements. Only 5 practitioners reported discontinuing OPJ because of undesired effects. Abdominal colic, nausea, and flatulence were the only adverse events reported by practitioners who recommended OPJ.

In addition to the practitioners who recommended OPJ, 76 (32%) responding practitioners were familiar with the use of OPJ but were yet to encounter a patient that they felt required the intervention. Demographic information about this group was similar to that of the practitioners who had recommended OPJ. Of the 76 practitioners, 80% of the practitioners believed

Table 2. Reported Use of OPJ Based on Survey Question Responses.

	Currently recommend (%) n = 149	Would recommend (%) n = 76
In what type of constipation do you recommend "Vaseline balls"? (please select all that apply)		
Hard stool in the rectum	84 (57)	40 (62)
Soft stool in the rectum	10 (7)	5 (8)
No stool in the rectum	31 (21)	14 (22)
Watery leakage but no formed stool	41 (28)	16 (25)
High impaction	106 (72)	30 (46)
Place in therapy		
First line	3 (2)	2 (3)
Second line (refractory to oral laxatives)	37 (26)	23 (35)
Third line (refractory to oral laxatives, suppositories, and/or enemas)	80 (55)	40 (62)
Not included in organizational protocols or educational material	40 (28)	
Duration of therapy		
Single dose	26 (18)	
<1 week	75 (52)	
1-2 weeks	24 (17)	
2-4 weeks	8 (6)	
>4 weeks	12 (8)	
Reason for discontinuation of therapy		
Ongoing regular bowel movements no longer requiring "Vaseline balls"	102 (73)	
No benefit observed	19 (14)	
Undesired effects	5 (4)	
Patient no longer able to swallow	46 (33)	
Patient died or actively dying	42 (30)	
Reported effectiveness		
Very effective—bowel movement in more than 75% of patients	57 (41)	
Effective—bowel movement in more than 50% of patients	63 (46)	
Somewhat effective—bowel movement in less than 50% of patients	16 (12)	
Not effective	2 (1)	
Time to stimulate bowel movement		
12 hours or less	33 (25)	
12-24 hours	84 (63)	
24-48 hours	15 (11)	
More than 48 hours	2 (1)	
Adverse events reported		
At least one of my patients has experienced an adverse event	4 (3)	
Many of my patients have experienced adverse events	1 (1)	
Abdominal colic	1 (<1)	
Nausea	1 (<1)	
Flatulence	2 (1)	

Abbreviation: OPJ, oral petroleum jelly.

OPJ should be used exclusively for adults, while the remainder felt OPJ could be used for adult and pediatric patients. As with those who had recommended OPJ, practitioners thought OPJ should be used primarily for high impaction and hard stool in the rectum, and many chose more than 1 form of constipation to target. Most practitioners felt OPJ should be reserved for third-line therapy (62%).

Of the 359 practitioners who completed this survey, 12 (5%) did not believe OPJ should be used (Table 3). All practitioners who felt OPJ should not be used served patients in urban/suburban or mixed areas and worked for hospices with an average daily census greater than 100 patients. Many had worked in hospice and palliative care for at least 10 years, and all had been health care providers for more than 10 years. There were practitioners from all represented disciplines who felt OPJ should not be used. The most commonly selected reason for opposing the use of OPJ was "this intervention would put my patients at an unnecessary risk of adverse events." One pharmacist specifically expressed concern about the risk of aspiration of a petroleum distillate by bed-bound patients or seniors with dysphagia. Other adverse events expected by those who opposed OPJ included lipid pneumonitis, choking, and nausea. The second most common explanation for opposing OPJ was the availability of multiple other therapeutic options to manage constipation. Three survey respondents raised concern that petroleum jelly is indicated for external use only, and 2 physicians reported "In my experience, this is not an effective intervention." No practitioner who opposed OPJ had learned of the intervention from an organizational bowel protocol. Most learned of the intervention from fellow health care providers, but 2 were introduced to the concept by nonhealth care professionals.

Table 3. Opposition to OPJ for Treatment of Constipation.

	Nursing, n = 4	Nurse practitioner, n = 5	Pharmacist, n = 1	Physician, n = 2	Total, n = 12
Reason for opposition to OPJ					
I believe this intervention would put my patients at an unnecessary risk of adverse events	1	4	1	1	7
There are enough alternative therapies available that my patients do not need to use "Vaseline balls"	3	2	–	1	6
Petroleum jelly is indicated for external use only	2	1	–	–	3
In my experience, this is not an effective intervention	–	–	–	2	2
Other		2	1	–	3
Adverse reactions expected in patients who use OPJ					
Abdominal colic	–	3	–	–	3
Nausea	–	3	–	1	4
Flatulence	–	1	–	1	2
Lipid pneumonitis with or without aspiration	1	3	1	1	6
Diarrhea	–	–	–	1	1
Anal leakage	–	1	–	1	2
Choking	1	3	–	1	5
Anal itching or irritation	–	1	–	–	1

Abbreviation: OPJ, oral petroleum jelly.

Proponents of OPJ have often described it as a safer alternative to oral mineral oil based on fluid consistency (semisolid vs liquid). Therefore, all practitioners who oppose OPJ were asked their opinion on oral mineral oil. Two practitioners reported they were comfortable recommending mineral oil for their patients despite being against OPJ. One practitioner expressed belief that petroleum jelly has a higher aspiration risk than mineral oil with more serious outcomes. The other practitioner cited the "external use only" labeling on petroleum jelly.

Discussion

This study demonstrates that many hospice and palliative care practitioners are familiar with the use of OPJ and have a positive opinion of the intervention. The high percentage (67%) of familiarity may be a reflection of hospice and palliative care practitioner openness to alternative therapies. Based on the goals of hospice and palliative care and difficulties with conducting research in this patient population, practitioners are more likely to try interventions that have anecdotally provided good symptom relief in the past regardless of how well the intervention has been documented in the literature. As no information has been published on the use of OPJ to date, it would make sense that the intervention is more common among those who have worked in palliative care for longer periods of time. Practitioners with more experience in hospice and palliative care were more likely to be familiar with OPJ and have recommended it for a patient they have encountered with hard to manage constipation. Hospice organizations are diligent in providing patients with appropriate prophylactic bowel regimens and there are a wide variety of bowel medications currently available. These facts coupled with the data that OPJ is most often used late in the course of treatment support the finding that among those who recommend OPJ, it is needed for less than 10% of patients with constipation. Practitioners newer to hospice are not likely to have the patient exposure to have been familiar with OPJ.

Based on data obtained from practitioners who oppose OPJ, we understand that information about OPJ appears to be most often shared by word of mouth from provider to provider and not through organizational protocols. With 87% of the practitioners describing OPJ as effective or very effective, it would be reasonable to believe the intervention would be passed on from practitioner to practitioner based on their positive experiences. One might have expected the reported effectiveness of OPJ to change depending on the type of constipation being treated. Based on the proposed mechanism of action, OPJ should work best for impacted fecal matter and hard stool in the rectum. Interestingly, the percentage of practitioners describing OPJ as effective or very effective remained relatively high even in those who recommended OPJ for other forms of constipation.

This study uncovered 2 interesting findings. First, although reportedly yielding effective or very effective results, OPJ appears to have a wide range of doses and frequencies. Second, the adverse event severity expected by practitioners that opposed the use of OPJ did not translate to the reported adverse effects described by those that use OPJ. Both findings have a significant impact on patient safety and will be important areas of study in the future. The most common reason for opposing OPJ among practitioners was the risk of adverse events. The adverse events that were expected by opposing practitioners including significant events such as lipid pneumonitis which is a potentially life-threatening condition that has only been reported in connection with oral mineral oil. In contrast, the adverse events witnessed with OPJ use (abdominal colic, flatulence, and nausea) may be expected with almost all bowel medications. This survey was not designed to correlate the dose of OPJ to the adverse events witnessed; therefore, data from this survey cannot be used to determine frequency of reported adverse events. Further

exploration of the adverse event profile of OPJ in a controlled prospective trial would be required to establish the adverse event profile and risk of lipid pneumonitis.

The method of survey distribution was selected to reach the largest number of potential respondents. Although the study met its goal of gathering responses from at least 270 practitioners, the ability to calculate the response rate was sacrificed. The number of study participants should indicate that survey responses are 95% accurate for at least 90% of hospice and palliative care practitioners, but survey responses were not evenly distributed across the United States. The number of survey respondents reporting familiarity with OPJ demonstrates widespread recognition primarily in the South and Midwest, but the high percentage may not be reflective of the overall hospice and palliative care community. Practitioners who are more familiar with OPJ may have been more likely to respond to the survey, as some practitioners exposed to the survey may have chose not to respond because they were unfamiliar with the intervention.

The results of this study clearly demonstrate that OPJ is not commonly used early in the management of most patients, but is widely recognized among hospice and palliative care practitioners as an effective therapy for the management of refractory constipation. The majority of practitioners was familiar with OPJ and had recommended them for their patients with positive results. Practitioners recommend OPJ for various forms of constipation and at a wide variety of doses. Although very few adverse events were reported by those who have recommended OPJ, an important area of future research will be a determination of the lowest commonly effective dose to produce a bowel movement. As familiarity with this intervention continues to grow it will also be important to establish the adverse event profile and quantify the risk of lipid pneumonitis in an effort to ensure patient safety.

Declaration of Conflicting Interests

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